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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,003	09/12/2001	Pasqua Oreste	MARGI 27 P1	9777

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/950,003

Applicant(s)

ORESTE ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-34, 38-53, 56-62, 64, 66, 68 and 70-77 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-34, 38-53, 56-62, 64, 66, 68 and 70-77 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

S.O.O.

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DETAILED ACTION

The amendment filed 1/24/2005 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-11, 35-37, 54-55, 63, 65, 67 and 69 have been canceled.
2. Claims 12, 32, 64 and 71 have been amended.
3. Remarks drawn to rejections under double patenting, 35 U.S.C. 112, first and second paragraphs,

Claims 12-34, 38-53, 56-62, 64, 66, 68 and 70-77 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

The allowability of claims 14-34 indicated in the previous office action has been withdrawn.

Double Patenting

The statutory double patenting (35 U.S.C. 101) of claims 1-10 as claiming the same invention as claims 1-10 of copending application No. 10/240606 ('606 application) has been rendered moot by cancellation of instant claims 1-10.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 14-34, 38-53, 56-62, 64, 66, 68 and 70-77 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 16-74 of copending Application No. 10/240606 ('606 application).

Claims 14-34, 38-53, 56-62, 64, 66, 68 and 70-77 are drawn to process of preparing glycosaminoglycans and recite limitations drawn to deacetylation sulfation, C-epimerization oversulfation, selective desulfation optional 6-o desulfation and N-sulfation, process times specific divalent cations to be used, reagents for sulfation, glycosaminoglycans comprising structural limitations, pharmaceutical compositions, method for controlling coagulation and method for treating and preventing thrombosis.

These same limitations are also recited in claims 16-74 of the copending '606 application.

Thus claims 14-34, 38-53, 56-62, 64, 66, 68 and 70-77 of the instant application and claims 16-74 of the copending '606 application are claiming the same invention as seen by the identical recitations.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection of instant claims 38-53 and 56-62 as being unpatentable over claims 30-31 of copending application No. 10/469,037 ('037 application) has been overcome in view of the arguments advanced by the applicants.

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The obviousness-type double patenting rejection of instant claims 4 and 11 as being unpatentable over claims 1-10 of copending application No. 10/240606 ('606 application) has been rendered moot by cancellation of the instant claims.

Claims 12-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 13 and 14 of copending Application No. 10/240606 ('606 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claims 12-13 are drawn to a process of preparation of K5 polysaccharide that recite process limitations comprising N-deacetylation, N-sulfation, C5 epimerization, oversulfation, O-desulfation, 6-O-sulfation and N-sulfation in the presence of glucuronosyl C5 epimerase and divalent cations, and process limitation regarding the time and reagent used in the 6-o sulfation step.

These same process limitations are also seen in claims 1, 4, 13 and 14 of the copending '606 application.

It would have been obvious to one of ordinary skill in the art that the instant claims 12-13 are substantially overlapping with claims 1, 4, 13 and 14 of the copending '606 application as stated above since the claims are drawn to the preparation of the same glycosaminoglycans involving the same steps and the skilled artisan would be motivated to use the same steps since the compounds have the same utility. Instant claims 12-13 should recite limitations that are patentably distinct from those of claims 1, 4, 13 and 14 of the copending '606 application.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The rejection of claims 66 and 70 under 35 U.S.C. 112, first paragraph as not enabling for the prevention of thrombosis is being maintained for reasons of record.

Applicants argue that the prior art publications submitted in support of their arguments show the use of low molecular weight heparins for the prevention of thrombosis and based on this the instant new glycosaminoglycans of their invention are enabled for prevention of thrombosis.

This is not found to be persuasive.

The instant compounds are C-5 epimerized glycosaminoglycans including other structural limitations that are different from heparins taught in the prior art. They are heparin like compounds. Even though they may exhibit anti-Xa and HCII activities as the same order as that of heparin they are still structurally different compared to heparin. One of ordinary skill in the art would not extrapolate the preventive efficacy of the instant compounds based on just the anti-Xa and HCII activity data. Prevention is seen as administering the instant compounds to a healthy subject and exposing the said subject to conditions that would induce thrombosis and showing that the instant compounds do prevent the said condition from manifesting. Applicants have not provided any examples involving animal or human models to demonstrate this. Hence one of ordinary skill in the art would have to perform undue experimentation in order to determine the

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preventive efficacy of the instant compounds for the said condition. The rejection is being maintained.

The rejection of claims 63, 65, 67 and 69 under 35 U.S.C. 112, second paragraph have been rendered moot by cancellation of the instant claims.

The rejection of claims 71-77 under 35 U.S.C. 112, second paragraph has been overcome by amendments.

The rejection of claims 64 and 68 under 35 U.S.C. 112, second paragraph is being maintained for reasons of record.

Applicants have amended the claim to recite the terms "regulating". The terms regulating is still seen to mean the same as the term control. The term regulating is interpreted to mean an increase or decrease or maintain as needed in order to bring the said condition to an innocuous level. The term is still not clear as to what applicants intend.

Conclusion

Claims 12-34, 38-53, 56-62, 64, 66, 68 and 70-77 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK


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